different methods of use. In addition, the Examiner alleged that the peptides of Groups I, III, V, VI, VIII, IX, XI, XII, XIV, XV, XVII, and XVIII are patentably distinct from each other because of their materially different amino acids sequences (Office Action at page 2, first paragraph). Furthermore, the Examiner alleged that within Groups III, VI, IX, XII, XV, XVI, XVII, XVIII, and XIX were patentably distinct sequences with materially different amino acid or nucleotide sequences. Additionally, the Examiner alleged that different searches would be required for each of the Groups I-XIX as well as for each sequence specified within the claims of Group III, VI, IX, XII, XV, XVI, XVII, XVIII, and XIX. On this basis the Examiner has asserted that searching all of the Groups and claimed sequences would constitute an undue burden upon the Examiner. The Applicants respectfully traverse the restriction imposed by the Examiner upon the election for examination of Group III, VI, IX, XII, XV, XVI, XVII, XVIII, and XIX in view of the reasons set forth below.

35 U.S.C. §121 states that "[i]f two or more independent and distinct inventions are claimed in one application, the Director **may** require the application to be restricted to one of the inventions (emphasis added)." The statute, therefore, establishes restriction as a procedural matter within the discretion of the Patent and Trademark Office Director. MPEP §803 provides Examiners with guidance as to when restriction is proper. Section 803 states "that there are two criteria for a proper requirement for restriction between patentably distinct inventions: the inventions must be independent or distinct as claimed; **and** there must be **a serious burden** on the Examiner if restriction is required (emphasis added)."

Although the Examiner concluded that the Applicants are required under 35 U.S.C. §121 to elect a single disclosed sequence if Applicants elect the invention of Group III, VI, IX, XII, XV, XVI, XVII, XVIII, or XIX, the Examiner failed to adequately support that conclusion in the Office Action. Importantly, the Examiner only provided broad and vague assertions that "different sequence searches would be required for each of the claimed sequences" generically claimed in claims 109, 111, and 113 of Group XV (for example, see Office Action, page 10, section 6). The standard applied by the Examiner in the present case then is clearly contrary to the controlling law described previously that demands that a failure to restrict **seriously** burden the Examiner before a restriction is considered proper. The Examiner provided no evidence of a serious burden actually existing in the absence of such a restriction. Furthermore, the Applicants contend that it would certainly not be a serious burden on the Patent Office if the second layer of restriction is not required amongst Group XV because of the very close similarity between the various sequences recited (SEQ ID NOS:202, 211, 219, 221, 231, 237 and 272). As clearly evidenced by the alignment of those sequences in the Table I below, each sequence differs only slightly from the others and differences are only found at one or both ends of the sequence. In other words, each sequence comprises

the same core sequence represented by SEQ ID NO:231. The Applicants respectfully contend that a sequence search using SEQ ID NO:231 as the query sequence would necessarily overlap and be sufficient for the examination of all sequences recited in group XV. The sequences recited within Group XV are so closely situated that there would be no serious burden on the Patent Office if restriction is not required because teachings on this type of subject matter are readily identified with sequence based searches. The advanced state of bioinformatics and sequence databases would presently allow for a single search using SEQ ID NO:231 would be sufficient to identify art disclosing the closest matching polypeptides known in the art. Upon identifying art using this query sequence it would be quite easy for the Examiner to determine whether or not the art discloses the other sequences (SEQ ID NOS :202, 211, 219, 221, 237 and 272) simply by comparing the 2, 3, or 4 amino acids preceding the core sequence and/or the 2 amino acids following the core sequence. Searches of divergent fields would certainly not be necessary for a thorough examination.

Table 1: Sequence alignment of Sequences within Group XV

SEQ ID NO:	Sequence of Peptide
202	QPTDQLGDWMLNYFRLVPPGTLE
211	PTDQLGDWMLNYFRLVPPGT
219	AQPTDQLGDWMLNYFRLVPPGTLE
221	PTDQLGDWMLNYFRLVPPGT
231	DQLGDWMLNYFRLVPPGT
237	PTDQLGDWMLNYFRLVPPGT
272	PTDQLGDWMLNYFRLVPPGT

Conclusion. In conclusion, Applicants assert that the Examiner did not adequately set forth reasons consistent with the law as outlined in MPEP §803 when imposing the restriction of the present application. For the foregoing reasons, Applicants respectfully assert that the second layer of the Restriction Requirement is improper. Therefore, Applicants respectfully request reconsideration and withdrawal of the second layer of the Restriction Requirement and examination on the merits of the whole of Group XV inventions.

Respectfully submitted,

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